

## **GREEN GUARD PAIN AND ACHE RELIEF- acetaminophen, aspirin, salicylamide and caffeine tablet**

**Unifirst First Aid Corporation**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Green Guard® Pain & Ache Relief**

#### ***Drug Facts***

#### **Active ingredients (in each tablet)**

Acetaminophen 110 mg

Aspirin (NSAID)\* 162 mg

Salicylamide (NSAID)\* 152 mg

Caffeine 32.4 mg

\*nonsteroidal anti-inflammatory drug

#### **Purposes**

Pain reliever/Fever reducer

Pain reliever/Fever reducer

Pain reliever

Pain reliever aid

#### **Uses**

#### **For the temporary relief of minor aches and pains associated with**

- headache
- muscular aches
- minor arthritis pain
- back pain
- common cold
- toothache
- menstrual cramps

**Temporarily reduces fever.**

#### **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin and Salicylates (NSAIDs) may cause a severe allergic reaction which may include:

- hives
- skin reddening

- facial swelling
- rash
- asthma (wheezing)
- shock
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains NSAIDs, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine- containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

#### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for pain for more than 10 days unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you ever have had an allergic reaction to any other pain relievers/ fever reducers
- right before or after heart surgery
- if you are taking prescription drugs for gout, diabetes, or arthritis

#### **Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have a history of stomach problems such as heartburn

#### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- under a doctor's care for any serious condition
- taking any other drug

#### **When using this product**

- take with food or milk if stomach upset occurs

#### **Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- symptoms do not improve
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding,** ask a health care professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

- **do not use more than directed**

### **Adults and children: (12 years and older)**

Take 1 or 2 tablets every 4 hours as needed. Do not take more than 8 tablets in 24 hours, or as directed by a doctor.

### **Children under 12 years:**

Do not give to children under 12 years of age.

### **Other information**

- read all product information before using
- tamper evident sealed packets
- store at room temperature 59°-86°F (15°-30°C)
- do not use any opened or torn packets

### **Inactive ingredients**

FD&C yellow #6, magnesium stearate, microcrystalline cellulose, povidone, starch, stearic acid.

### **Questions or Comments? 1-800-869-6970**

### **Principal Display Panel – Box Label**

Pain & Ache Relief

Green Guard®

Pull Out

Tabletas para aliviar el dolor

Acetaminophen/Acetaminofeno 110 mg

Aspirin (NSAID)/Aspirina (AINE) 162 mg  
Salicylamide (NSAID)/Salicilamida (AINE)152 mg  
Caffeine/Cafeina 32.4 mg  
125 packets of 2 tablets  
250 Tablets Order #2210  
Distributed by Green Guard®, St Louis, MO 63045



# GREEN GUARD PAIN AND ACHE RELIEF

acetaminophen, aspirin, salicylamide and caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-003
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	110 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	162 mg	
SALICYLAMIDE (UNII: EM8BM710ZC) (SALICYLAMIDE - UNII:EM8BM710ZC)		SALICYLAMIDE	152 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	32.4 mg	
Inactive Ingredients				
Ingredient Name			Strength	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONE (UNII: FZ989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	orange (orange)	Score	no score	
Shape	ROUND (ROUND)	Size	11mm	
Flavor		Imprint Code	FR;2	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-003-33	50 in 1 BOX, UNIT-DOSE		
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-003-48	125 in 1 BOX, UNIT-DOSE		
2	NDC:47682-003-99	2 in 1 PACKET; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part343	12/30/2008	

**Labeler** - Unifirst First Aid Corporation (832947092)